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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,717	12/04/2003	Stephen P. Arneric	3612/US	6897

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,717	ARNERIC, STEPHEN P.	
	Examiner	Art Unit	
	Chris Simmons	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 11, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition, comprising administering 6-[[5-(4-chlorobenzoyl)-1,4-dimethyl- 1H-pyrrol-2-yl]methyl]-3(2 H)-pyridazinone or a prodrug thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 570, subclass 182.

II. Claim 12-21, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition, comprising administering the recited Cox-2 selective inhibitors in claims 12-21 or prodrugs thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 546 and 549.

III. Claim 24, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition,

comprising administering the recited Cox-2 selective inhibitors recited in claim 24 or prodrugs thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 540-549.

IV. Claim 25, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition, comprising administering the recited Cox-2 selective inhibitors recited in claim 25 or prodrugs thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 548, subclass 240

V. Claim 26, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition, comprising administering the recited Cox-2 selective inhibitors recited in claim 26 or prodrugs thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 544, and subclass 224

VI. Claim 27-28, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition, comprising administering the recited Cox-2 selective inhibitors recited in claims 27-28 or prodrugs thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 544, subclass 224

VII. Claim 29-30, drawn to a method for the treatment, prevention, or inhibition of a CNS disorder, pain and inflammation, or an inflammation-associated disorder in a subject in need of such treatment, prevention, or inhibition, comprising administering the recited Cox-2 selective inhibitors recited in claim 29-30 or prodrugs thereof and venlafaxine, atomoxetine, and duloxetine, classified in class 570, subclass 310

Currently, claims 1-10, 22-23, and 31-68 are generic.

2. Claims 1-10, 22-23, and 31-68 link inventions I-VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, 1-10, 22-23, and 31-68. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other because of the following reasons: This application contains claims directed to the following patentably distinct species: a composition comprising of COX189 and venlafaxine, atomoxetine, or duloxetine, a composition comprising of a rofecoxib and venlafaxine, atomoxetine, or duloxetine, a method of treating Alzheimer's disease, a method of treating meningitis, and a method of treating menstrual cramps. The species are independent or distinct. For example, Alzheimer's is a disease caused by abnormally folded amyloid beta protein in the brain and can be treated with acetylcholinesterase inhibitors; whereas, menstrual cramps is pain that can be treated with Tylenol®. Moreover, COX189 may be used for treatment of cardiovascular disease and rofecoxib may be used to treat osteoarthritis.

4. Applicant is required under 35 U.S.C. 121 to make an election of species. This application contains claims directed to the following patentably distinct species:

a. Disease (DX): CNS disorder, pain, inflammation

b. Combination of compounds (composition): (i) a COX-2 inhibitor (e.g. formula as recited in claim 11, a specific chromene compound as recited in claim 13, etc) + (ii) a compound (i.e. duloxetine, venlafaxine or atomoxetine).

c. **Dosage regimen: sequential administration or simultaneous administration as recited in claims 48 and 49.**

Each disease (condition as claimed) is considered to be patentably distinct as well recognized by a skilled artisan because they require different treatment and materially different therapeutic modalities. The compounds as recited in claim 11 and 13 have chemically different structures and are also classified differently. Therefore, each species is patentably distinct and a search of the genus as claimed would be burdensome for the examiner. Consequently, the applicant must make an election of a single disclosed COX-2 selective inhibitor and a single disclosed SSRI/NRI compound from the group comprising atomoxetine, venlafaxine, and duloxetine. Upon the election of species, applicant is further required to elect a single disclose species of disease (e.g. Alzheimer as recited in claim 50; or Crohn's disease as an inflammatory disease as recited in claim 39).

5. Applicant is advised that a reply to this requirement must **include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on M-F from 7:30 - 5:00 PM EST.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang or Andrew Wang, can be reached on (571) 272-1600 or (571) 272-0811, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chris Simmons CS

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600